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| EXAMINER |
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LI, QIAN J

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| ART UNIT | PAPER NUMBER |
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1632

DATE MAILED: 11/19/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

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|-----------------|--------------|--------------|-----------------|
| Application No. | 09/890,351 | Applicant(s) | ASASHIMA ET AL. |
| Examiner | Q. Janice Li | Art Unit | 1632 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 September 2002.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 18-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 18-27 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. ____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). ____ .
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ . 6) Other: ____ .

DETAILED ACTION

The amendment, response, and Declaration filed 9/10/02 have been entered as paper #8. Claims 1-17 have been cancelled, claims 18-27 are newly submitted and are pending in the application and under current examination.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims will not be reiterated. The argument would be addressed to the extent that apply to the present rejections.

Information Disclosure Statement

In view of the submission of International Search Report in English, which indicated the degree of relevance of IDS AA, AC, AD, and AE, these documents have been considered to the extent that indicated in the search report. However, the relevance of AF was not indicated in the international search report.

Further, it is noted that certain documents cited in the IPEA box VIII have not been disclosed in PTO-1449.

Drawings

The newly submitted drawings contain color photographs. Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) is granted permitting their use as acceptable drawings. In the event that applicant wishes to use the drawings currently on file as acceptable

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drawings, a petition must be filed for acceptance of the color photographs or color drawings as acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the U.S. Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

ENABLEMENT REQUIREMENT

The prior rejection of claims 1-10 now applies to new claims 18-23, and 25-27, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants argue in paper #8 that the specification described "for examination of the cell differentiation or the stages, it is preferable to conduct quantitative analysis using many kinds of gene markers or antibodies simultaneously with observation of the tissue", "more defined testing can be performed by using genome DNA as stage

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markers for practice the invention", and "the basic rule of body formation is common to all the vertebrates and homologous genes are known to have quite a similar function among different species", that the method of constructing clones of xenopus and sheep can be obtained by the same methods, therefore, no undue experimentation is required for practice the invention. The applicant filed a Declaration to indicate "in case a particular organ in a particular vertebrate is targeted, the person skilled in the art can easily determine which gene DNA can be used as stage markers by ordinary methods such as the differential display method", that the Examiner admits that Asashima et al, Ariizumi et al anticipates or obvious over the instant claims.

The arguments have been fully considered but they are not persuasive for reasons of record and following.

First, the cited art of Asashima et al and Ariizumi et al are drawn to methods of cultivating organs of a Xenopus, they anticipate or obvious over a particular embodiment, but not the full scope of the claims.

Second, even though the principle of basic differentiation such as development, cell and organ differentiation is common to all vertebrates, practicing the claimed invention requires specific, not a sketchy guidance as reiterated by the applicants and cited above. The claims now list genome DNA analysis and cultivation of a particular part of the ectoderm as the inventive step, if these could be done by the knowledge of general principles, they would not be considered as invention. In practicing step i) of claims 18 or 25, it requires precise correlation of distinguishable and unique gene markers correspondent to a particular developmental stage for each genus, subgenus,

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and species of vertebrates, such markers may not be easily determined by a simple DNA genome search and screening. The developmental gene markers may be known for a few most commonly studies species, they are not known for most of the vertebrates. In fact, the specification fails to disclose even one developmental stage marker for the species of *Xenopus*, let alone the entire vertebrate genus. The Federal Circuit has stated that: "A SPECIFICATION NEED NOT DISCLOSE WHAT IS WELL KNOWN IN THE ART. SEE, E.G., HYBRITECH INC. v. MONOCLONAL ANTIBODIES, INC., 802 F.2d 1367, 1385, 231 USPQ 81, 94 (FED. CIR. 1986). HOWEVER, THAT GENERAL, OFT-REPEATED STATEMENT IS MERELY A RULE OF SUPPLEMENTATION, NOT A SUBSTITUTE FOR A BASIC ENABLING DISCLOSURE. IT MEANS THAT THE OMISSION OF MINOR DETAILS DOES NOT CAUSE A SPECIFICATION TO FAIL TO MEET THE ENABLMENT REQUIREMENT. HOWEVER, WHEN THERE IS NO DISCLOSURE OF ANY SPECIFIC STARTING MATERIAL OR OF ANY OF THE CONDITIONS UNDER WHICH A PROCESS CAN BE CARRIED OUT, UNDUE EXPERIMENTATION IS REQUIRED; THERE IS A FAILURE TO MEET THE ENABLMENT REQUIREMENT THAT CANNOT BE RECTIFIED BY ASSERTING THAT ALL THE DISCLOSURE RELATED TO THE PROCESS IS WITHIN THE SKILL OF THE ART. IT IS THE SPECIFICATION, NOT THE KNOWLEDGE OF ONE SKILLED IN THE ART, THAT MUST SUPPLY THE NOVEL ASPECTS OF AN INVENTION IN ORDER TO CONSTITUTE ADEQUATE ENABLMENT." Genentech Inc. v. Novo Nordisk A/S, 42 USPQ2d 1005 (CAFC 1997) (emphasis added).

In practicing the step ii) of claims 18 or 25, it requires precise knowledge with regard to the type, amount, and timing of the growth factors required for proper development for each type of vertebrate, such knowledge may not be predictably extrapolated from *Xenopus*. As cited in the previous Office action and reiterated here, "THE MOLECULAR BASIS OF THE SELF-RENEWING PLURIPOTENT PHENOTYPE REMAINS ILL-DEFINED.

THE RELATIONSHIP BETWEEN FACTORS THAT INFLUENCE EMBRYONIC STEM CELLS PROPAGATION IN VITRO AND MECHANISMS OF STEM CELL REGULATION OPERATIVE IN THE EMBRYO IS ALSO UNCERTAIN" (*Burdon et al, Cells Tis Org 1999;165:131-34*). *Hardy et al (J Endocrinol 2002;172:221-36)* teach that human development is regulated by embryonically and maternally derived growth factors of various kinds at different stages of the embryo development. These growth factors and their receptors would influence the *rate* of embryo development, the *proportion* of embryos developing to the blastocyst stage, blastocyst cell number, *metabolism and apoptosis* by ways of autocrine, paracrine, and endocrine pathways that may operate within the embryo and between the embryo and the reproductive tract.

Even though the method of cloning is common in principle among different vertebrates, the phenotype of cloned vertebrate animals differs significantly, for example, a simple look of the appearance of a *xenopus* and a sheep would find that they differ in so many ways. Such differences are determined by the genome components as well as cytokines and growth factors during the development. The unpredictability of animal cloning technology lies not on the method steps but the substantial differences in development and resulting phenotypes. Therefore, it is difficult for one skilled artisan to predictably extrapolate from disclosed condition for the development of a *xenopus* to that of any organ of any vertebrate animal, because the cytokine ligands, cellular receptors, the complicity of maternal environments differ among different organs of a vertebrate, and among different subgeneruses of vertebrates such as amphibian, bird, fish, and mammal. The cytokines that function in certain stage

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of a *Xenopus* may not be effective in fish or human. IL-11 is required for the development of lymphocytes but not that of leukocytes, for example. In addition, organs such as heart or kidney are known to be derived from mesoderm (see EB reference). Although applicants demonstrated that the ectoderm region of *Xenopus* could differentiation to pronephron under certain conditions, the specification fails to teach whether organs such as heart could also be differentiated from the animal cap, what such conditions are.

The physiological art in general is acknowledged to be unpredictable (MPEP 2164.03). It is noted that in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. In re Soll, 97 F.2d 623, 38 USPQ 189 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. In re Fisher, 166 USPQ 18 (CCPA 1970). See also In re Wright, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993); In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one species, what other species will work. In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "IT IS WELL SETTLED THAT IN CASES INVOLVING CHEMICALS AND CHEMICAL COMPOUNDS, WHICH DIFFER RADICALLY IN THEIR PROPERTIES IT MUST APPEAR IN AN APPLICANT'S SPECIFICATION EITHER BY THE ENUMERATION OF A SUFFICIENT NUMBER OF THE MEMBERS OF A GROUP OR BY OTHER APPROPRIATE LANGUAGE, THAT THE CHEMICALS OR CHEMICAL COMBINATIONS INCLUDED IN THE CLAIMS ARE CAPABLE OF ACCOMPLISHING THE DESIRED RESULT."

Accordingly, for reasons of record and set forth above, the rejection stands.

WRITTEN DESCRIPTION REQUIREMENT

The prior rejection of claim 11 applies to claim 24 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants argue in paper #8 that the post-filing publication have shown the same method has used to develop multiple organs from *Xenopus*, that applicants are entitled to the full scope of the invention because other patents relating to basic DNA recombination technology have broad claims from one example.

The arguments have been fully considered but they are not persuasive for reasons of record and following.

Evidently, even at the post-filing dates, there is no evidence that the claimed method is applicable to a vertebrate other than *Xenopus*. Therefore, the statement in the Revised Interim Guidelines is fully applicable here, "WHEN THERE IS SUBSTANTIAL VARIATION WITHIN THE GENUS, ONE MUST DESCRIBE A SUFFICIENT VARIETY OF SPECIES TO REFLECT THE VARIATION WITHIN THE GENUS", "IN AN UNPREDICTABLE ART, ADEQUATE WRITTEN DESCRIPTION OF A GENUS WHICH EMBRACES WIDELY VARIANT SPECIES CANNOT BE ACHIEVED BY DISCLOSING ONLY ONE SPECIES WITHIN THE GENUS" (Column 2, page 71436). Considering the potential numbers of organs encompassed by the claims, in view of the variations in genome components, cytokines, growth factor and receptors, and the complex mechanisms of

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embryonic development, the disclosed organs are not the representative species of the genus.

With respect to arguments that there are issued patents having broad claims, the court (*In re Giolito and Hofmann*, 188 USPQ 645 (CCPA 1976)) states "IT IS IMMATERIAL WHETHER SIMILAR CLAIMS HAVE BEEN ALLOWED TO OTHERS. See *In re Margaroli*, 50 CCPA 1400, 318 F.2d 348, 138 USPQ 158 (163); *In re Wright*, 45 CCPA 1005, 256 F.2d 583, 118 USPQ 287 (158); *In re Launder*, 41 CCPA 887, 212 F.2D 603, 101 USPQ 391 (1954)." Each application is examined on its own merits and cannot be compared to other application.

Accordingly, for reasons of record and those set forth above, the rejection stands.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-27 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 18-~~23~~? are vague and indefinite. The claims are directed to a method for preparation of an *in vitro* induced organ, such organ could only be prepared by organ culture. However, step i) is drawn to examination of genome DNA, which is irrelevant to organ cultures; claim 23 is drawn to the recipient of a transplant graft, which is relevant to a method for transplantation but irrelevant to a method of culturing an organ, it is

unclear what method the applicants intend to claim, organ culture preparation or organ transplantation.

The claims are vague and indefinite. The claims recite determining the stage of the development in a recipient by an examination of genome DNA, however, no active and positive steps are provided, and it is unclear how the genome DNA is examined. Method claims need not recite all operating details but should at least recite positive, active steps so that the claims will set out and circumscribe a particular area with a reasonable degree of precision and particularity and make clear what subject matter that claims encompass as well as make clear the subject matter from which others would be precluded, *Ex parte Erlich*, 3 USPQ2d 1011 at 6.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following rejections still apply because of the standing 112 § 2 rejection drawn to a DNA examination step improperly placed in a method for organ culture.

Claims 18, 22, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by *Stice et al* (US 2001/0039667).

In paper #8, applicants argue that claimed invention means an organ induced by culturing from non-differentiated cells *in vitro*. *Stice et al.* dose not induce the organ for transplantation.

The argument has been fully considered but found not persuasive because "for transplantation" only states the intended use, not the method steps for culturing. *Stice et al* teach a method for *in vitro* induced ungulate embryos and offspring, which may be derived from ectoderm (0098, page 8) as required by the claims. Because every stage of such cultured organ would find a corresponding recipient, the teaching of *Stice et al* meets claim limitation. Thus, *Stice et al* anticipate the instant claims.

Claims 18-22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by *Asashima et al* (Proc Natl Acad Sci USA 1991 Aug;88:6511-14).

Applicants argue in paper #8 that *Asashima et al.* does not induce organ for transplantation, only teach the differentiation of explants to organs and its relation with activin A. They do not teach induction from non-differentiated cells to organs, nor do they teach transplanting such *in vivo*. In fact, Professor *Asashima* has declared that "when I wrote these papers, I did not think about transplantation at all".

The arguments have been fully considered but they are not persuasive for reasons of record and following.

Asashima et al clearly teach a method for preparation of *in vitro* induced organs, such as notochord, muscle, mesenchyme, and epidermis (fig. 2). The organs are induced from early *Xenopuse* (vertebrate) animal-cap cells (ectoderm of a stage 9 blastula), which meets the claim limitation, wherein the cells are cultured in the presence of activin (EDF, left column of page 6512). *Asashima et al* teach that different genes may express at different stages of the embryo development, such as Xar9 (paragraph bridging columns in page 6513). Because every stage of such organ would find corresponding recipient, the teaching of *Asashima et al* meets claim limitation. Thus, *Asashima et al* anticipate the instant claims.

Please note that intended use limitations bear little weight on the determination of novelty of the invention. In this case, "for transplantation that functions *in vivo* when transplanted into a recipient" does not carry patentable weight in the determination of anticipation for the claimed products or methods. This is because a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). It is a general rule that **merely discovering and claiming a new benefit to an**

old process cannot render the process again patentable. *In re Woodruff* 919 F. 2d 1575, 1577-78, 16 USPQ2d 1934, 1936-37 (Fed. Cir. 1990); *In re Swinehart*, 439 F. 2d 210, 213, 169 USPQ 226, 229 (CCPA 1971); and *Ex Parte Novitski*, 26 USPQ2d 1389, 1391 (Bd. Pat. App. & Int. 1993). (emphasis added)

Claims 18-22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by *Ariizumi et al* (Int J Dev Biol 1991;35:407-14).

Applicants do not provide argument for this rejection; therefore, it stands for reasons of record and the immediate proceeding paragraphs.

Claims 18-22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by *Asashima et al* (Dev Biol 1990;198:330-335, PTO-1449/AG).

Applicants do not provide argument for this rejection; therefore, it stands for reasons of record and the immediate proceeding paragraphs.

Claims 18-20, 22, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by *Yokota et al* (Biochem Biophys Res Communications 1995 Feb;207:1-7), as evidenced by *Asashima et al* (Dev Biol 1990;198:330-335, PTO-1449/AG).

Applicants argue in paper #8 that *Yokota et al* have not induced organs *in vitro* from non-differentiated cells, nor prepared organs for transplantation.

The argument has been fully considered but found not persuasive for reasons of record and following.

Yokota et al teach culturing explants from the animal hemisphere of *Xenopus* embryos in the presence of activin A, thus, meets claim limitation as "culturing an organ induced from ectoderm region which has been cut off from the blastula". Because every stage of such organ would find corresponding recipient, the teaching of *Yokota et al* meets claim limitation. Thus, *Yokota et al* anticipate the instant claims.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li
Examiner
Art Unit 1632

QJL
November 15, 2002

ANNE M. WEHBE PH.D
PRIMARY EXAMINER

